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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. 2:15-MD-02641-DGC

DEFENDANTS' REPLY IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 1 TO EXCLUDE EVIDENCE OF RECOVERY® FILTER COMPLICATIONS AND OTHER COMPLICATIONS THAT ARE NOT SUBSTANTIALLY SIMILAR TO THE INCIDENT AT ISSUE

(Assigned to the Honorable David G. Campbell)

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Plaintiff seeks to try this case not based on any identifiable defect in the G2 Filter, but based on the sheer number of complaints that Bard has received about its entire line of retrievable IVC filters. *See* Pl.'s Ex. F to Pl.'s Resp. (Doc. 10068-6). She has compiled a chart of summary information from **949** adverse event reports involving the Recovery, G2, G2X, G2 Express, and Eclipse Filters "on which Plaintiff intends to rely on at trial" to prove her "defective design claims," among other issues. (Pl.'s Resp. at 3, 7.) Plaintiff should not be permitted to avoid her burden of proving a defect by presenting voluminous complaint data. *See, e.g.*, *Nissan v. Armstrong*, 145 S.W.3d 131, 140 (Tex. 2004) ("[A] large number of complaints cannot alone raise a fact question that a defect exists.").

Nor should Plaintiff be allowed to avoid her burden of making a particularized showing that ***"each"*** incident that she "intends to rely on at trial" is substantially similar to the incident in suit. *St John v. Toyota Motor Corp.*, No. 8:10ML02151 JVS FMOX, 2013 WL 5775081, at *5 (C.D. Cal. Oct. 11, 2013) (emphasis added); *Cooper v. Firestone Tire & Rubber Co.*, 945 F.2d 1103, 1105 (9th Cir. 1991) ("A showing of substantial similarity is required when a plaintiff attempts to introduce evidence of other accidents as direct proof of negligence, a design defect, or notice of the defect.").

Plaintiff asks this Court to ignore binding Ninth Circuit precedent and create new law for this "unique situation" without any legal support, contending that existing authority is inapplicable. (Pl.'s Resp. at 4.) But federal courts have had no issue following the substantial similarity doctrine in cases involving 510(k)-cleared devices. *See, e.g.*, *Schenone v. Zimmer, Inc.*, No. 3:12-CV-1046-J-39MCR, 2014 WL 12619911, at *1 (M.D. Fla. Aug. 27, 2014) (excluding "Medical Device Reports ("MDR's") and Adverse Event Reports . . . [b]ecause Plaintiffs have not established substantial similarity between the facts underlying the MDR's and Adverse Events reports and the facts of the instant case."); *Moon v. Advanced Med. Optics, Inc.*, No. 4:08-CV-0021-HLM, 2010 WL 11500832, at *5 (N.D. Ga. Dec. 29, 2010) (excluding MAUDE reports because "Plaintiffs have produced only cursory evidence, which fails to satisfy their burden to prove [substantial similarity]," and because the MAUDE reports "are inadmissible hearsay").

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A. Plaintiff Fails to Carry Her Burden of Proving That Each Other Incident Is Substantially Similar to Her Case, Instead Shifting Her Burden to The Court.

Plaintiff concedes that, as the proponent of this evidence, she bears the burden of showing substantial similarity. (*See* Pl.'s Resp. at 4). Plaintiff cannot shift her burden to Bard to show dissimilarity. *See, e.g.*, *Hale v. Firestone Tire & Rubber Co.*, 756 F.2d 1322, 1332 (8th Cir. 1985) ("[The] district court erred in admitting evidence of [other incidents] and in shifting to [defendants] the burden of showing dissimilarity after the evidence was admitted."). Nor can she "improperly shift the burden to the Court" to review cursory evidence to find "support for Plaintiff's claim of substantial similarity." *Steede v. Gen. Motors, LLC*, No. 11-2351-STA-DKV, 2013 WL 142484, at *9 (W.D. Tenn. Jan. 11, 2013). Yet that is exactly what Plaintiff is asking the Court to do here.

Plaintiff asks this Court to review the **949** adverse events that she has compiled involving five different Bard filters (only one of which -- the G2 Filter -- Plaintiff actually received) and directs the Court generally to "each and every 510(k) submission for *all* of its filters," and her entire 314-paragraph Omnibus Statement of Facts (Doc. 8186), to find the "broad foundation for the substantial similarities that exist as to the common design of the Recovery, G2, G2X/Express, and Eclipse filters." (Pl.'s Resp. at 5-6.) She then summarily asserts that all **949** of the incidents involving these different products are no "different from" and "do not deviate" from the incident in suit. (*Id.* at 7.) But the substantial similarity analysis "requires a detailed consideration of each [incident]." *St John*, 2013 WL 5775081, at *5. Indeed, because of this requisite analysis, one MDL court in this circuit recently limited the plaintiffs to presentation of only ***ten*** other incidents at trial and ordered plaintiffs to submit detailed briefing demonstrating substantial similarity of each incident. *Id.* Plaintiff's proffer for the **949** incidents here is woefully insufficient.

For example, Plaintiff has made no showing whatsoever as to how each of the alleged incidents of Recovery Filter cephalad migration of the ***entire filter*** to a patient's heart is at all similar, let alone "substantially similar," to Plaintiff's alleged G2 Filter "caudal migration" (i.e., downward) and embolization of a fractured strut (***not*** the entire

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filter) to her heart, (Pl.'s Resp. at 7 n.9), as is her burden.[1] Instead, Plaintiff argues that these medically distinct complications are substantially similar because Bard grouped them together in internal reports and in reports to FDA. This assertion is misleading.[2] In fact, in the very document on which Plaintiff relies, Bard's February 2006 Health Hazard Evaluation, Bard identifies the distinct "potential risks to patients of cephalad migration events" separate and apart from the "possible adverse outcomes" associated with "filter migration in either direction." Pl.'s Ex. I to Pl.'s Resp. at BPVEFILTER-01-00008356.[3] Also, Bard highlighted medical literature in its Motion that discussed these differences, (*see* Mot. at 2 n.2), and Plaintiff has cited no literature or other evidence to rebut them.

Critically, Plaintiff did not even attempt to show how the small number of alleged incidents of Recovery Filter cephalad migrations to patients' hearts resulting in patient death,[4] are substantially similar to Plaintiff's alleged G2 Filter caudal migration and strut embolization that she survived. Nor does she rebut the substantial prejudice that this irrelevant and inflammatory evidence would cause Bard, or the likelihood that the "jury could easily be confused or misled [by this evidence] into imposing liability on the mere basis of what *could* have happened rather than what *did* happen." *See Bauerlein v. Equity Residential Properties Mgmt. Corp.*, No. CIV 04-1904 PHXSMM, 2007 WL 1546101, at *1 (D. Ariz. May 24, 2007) (excluding evidence of other incidents involving death under FRE 403); Fed. R. Evid. 403. These are but a handful of examples of dissimilar incidents from the **949** adverse events that Plaintiff intends to rely on in this case.

B. "Substantial Equivalence" Is Not the Same as "Substantial Similarity."

[1] *See, e.g.*, Pl.'s Ex. F (Complaint ID Nos. 9741, 12431, 16312, 18005, 21832, 25608, 30041, 34006, 34126, 43942, 49067, 57667, 85081, 235413, and 359602).
[2] Bard was limited to using the FDA-authorized device code for migration (FDA 1395) in its MDRs to FDA, *see* 21 C.F.R. § 803.52(f)(6), which is not IVC filter specific and did not differentiate between cephalad or caudal migration. Regardless, Bard did describe migrations as cephalad or caudal in the narrative sections of the MDRs if it was aware of such. Further, Bard used internal sub-device codes for caudal (1395O) and cephalad (1395P) migrations for internal trending purposes. *See* MDR Reportability Guidelines IVC Filters, FM1287100 at BPV-17-01-00232754, excerpts attached hereto as Exhibit B.
[3] Bard also stratified caudal and cephalad migration as part of its G2 Filter risk analysis. *See* DFMEA070022 at BPV-17-01-00139805-816, excerpts attached hereto as Exhibit C.
[4] *See, e.g.*, Pl.'s Ex. F (Complaint ID Nos. 9742, 12431, 21832, and 30041).

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As mentioned in Bard's Motion, that the Recovery Filter and the G2 Filter are "substantially equivalent" under the applicable FDA regulations does not render complications involving the Recovery Filter *per se* "substantially similar" to the G2 Filter. Substantially equivalent devices can have different technological characteristics. *See* 21 U.S.C. § 360c(i)(1)(A). Indeed, the Court need only compare the different technological characteristics between the Simon Nitinol Filter and the "substantially equivalent" Recovery Filter. *See* Ex. A to Mot. (Doc. 9862-1). That these devices are substantially equivalent does not render them *per se* substantially similar under the legal standard.

Bard identified in its Motion the important design changes that it made to the Recovery Filter when developing the G2 Filter based on its clinical experience with the Recovery Filter. (*See* Mot. at 10.) Bard made these dimensional changes to the design aimed specifically at improving fracture and cephalad migration resistance over the Recovery Filter design, which Plaintiff conceded. *See* Doc. 7950 at ¶ 63. Clinical experience proved the impact of these design improvements on the performance of the G2 Filter, which Plaintiff also conceded. (*See* Pl.'s Resp. at 3 n.1.)[5]

Contrary to Plaintiff's contention, Bard adequately explained and illustrated all of these design changes in its 510(k) submission, including the design verification and validation activities affected by and completed for the design changes in Section IV. *See* Pl.'s Ex. A to Pl.'s Resp. at BPV-17-00125355-369.[6] While these changes were primarily dimensional, their impact on the performance of the G2 Filter belies any substantial similarity with the Recovery Filter.[7] *See Lewy v. Remington Arms Co.*, 836 F.2d 1104,

[5] Plaintiff argues that Bard trended Recovery Filter adverse events together with the G2 Filter and Bard's other filters, but the very document on which Plaintiff relies shows that Bard trends Recovery Filters separately from its other filters. *See* Pl.'s Ex. F to Pl.'s Resp.

[6] Plaintiff makes much of the fact that the original trade name for the G2 Filter was the "Recovery Filter." But Bard submitted the design of the G2 Filter for FDA 510(k) review, not the name. The trade name has no impact on the fact that Bard made significant dimensional changes to the design of the Recovery Filter, which saw significant improvements to fracture and migration resistance as demonstrated by Bard's clinical experience. If a trade name was the legal standard, then, for example, evidence involving a first-generation Ford Explorer (1990 to 1994) would always be substantially similar to a fifth-generation Ford Explorer (2010 to present), regardless of their design differences.

[7] To the extent Plaintiff contends that Bard attested in its 510(k) submission that the G2 Filter "is similar in all material ways" to the Recovery Filter, (Pl.'s Resp. at 10), relying

1109 (8th Cir. 1988) (noting that even minor dimensional changes to a product, including a "change in the tolerances as small as the width of a human hair," can have a large impact on product performance, making the two products not substantially similar).

C. Plaintiff's Other Incidents Are Not Relevant to Prove "Notice."

Plaintiff intends to use the **949** adverse events to prove her "defective design claims," "punitive damages, warnings," and much more, not just to prove Bard was on "notice." (Pl.'s Resp. at 3-4.)[8] Even if Plaintiff can meet a lesser showing for notice, which Bard denies, Plaintiff cannot circumvent the required showing of "substantial similarity" simply because she also seeks to use the evidence for notice. *See Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-cv-00837, 2012 WL 1113955, at *2 (S.D. W. Va. Mar. 30, 2012) (precluding use "of other incidents as evidence of a product defect or negligence without establishing substantial similarity," but allowing evidence for notice). Indeed, to use this evidence to prove defect, courts require "a high degree of similarity because it weighs directly on the ultimate issue to be decided by the jury." *Wheeler v. John Deere Co.*, 862 F.2d 1404, 1407 (10th Cir. 1988). Further, as explained in its Motion, Bard's "notice" of the potential for a G2 Filter to move, perforate, migrate, or fracture is not contested by Bard in this case; therefore this evidence has little, if any, probative value on the issue of notice. *See Thomas v. Bombardier Recreational Prods., Inc.*, No. 2:07-cv-730-FtM-29SPC, 2010 WL 4188308, at *2 (M.D. Fla. Oct. 20, 2010).

CONCLUSION

For all of these reasons, and the reasons raised in its Motion, Bard respectfully requests that the Court grant its Motion.

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on language that "No material changes or additional components have been incorporated, (*see* Doc. 10050 at 2 (emphasis added by Plaintiff)), this contention is disingenuous and misleading. This quoted language refers to the fact that Bard made no changes to the raw material for the G2 Filter, ***not*** that the design changes were "immaterial" as Plaintiff suggests. (*See*, *e.g.*, Doc. 10050 at 3, 4 ("Bard[made] representations that the differences between the Recovery and G2 were 'primarily dimensional' and not 'material'"; "Bard made insignificant and immaterial design changes"); Pl.'s Resp. at 10 ("The FDA submission represents [] the G2 is similar in all material ways to [the] Recovery Filter.").

[8] Contrary to Plaintiff's continued insistence, there is no general "negligence" claim in this case. *See* Doc. 9644. Further, Plaintiff fails to explain how this evidence is probative of her design defect claim under Georgia law.

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RESPECTFULLY SUBMITTED this 16th day of February, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of February, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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